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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,464	08/15/2005	Tohru Natsume	081356-0235	8195
22428 7590 12/04/2007 FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			EXAMINER BORIN, MICHAEL L	
			ART UNIT 1631	PAPER NUMBER
			MAIL DATE 12/04/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/526,464

Applicant(s)

NATSUME ET AL.

Examiner

Michael Borin

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) 3 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 03/03/2005 and 09/21/2006.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1-3 are pending.

Response to restriction requirement filed 10/01/2007 is acknowledged. Applicant elected, without traverse, Group I, claims 1,2. Claim 3 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected group.

Priority

2. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed on 03/03/2005.

Information Disclosure Statement

3. Applicants' Information Disclosure Statements filed 03/03/2005 and 09/21/2006 have been received and entered into the application. Accordingly, as reflected by the attached completed copies of forms PTO-1449, the cited references, except for JP-10-132786 application, have been considered.

With respect to the JP-10-132786 application, 37 CFR 1.98(a)(2) requires a legible copy of each cited foreign patent document. No copy of the application has been furnished. Further, the information disclosure statement filed 03/03/05 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c)

most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-2 are rejected under 35 U.S.C. 102(a) as anticipated by Egelhofer (Anal. Chem., 74, 1760-1771, March 3 2002)

The instant claims are drawn to method for automatic identifying of biopolymers comprising the steps:

- A mass measurement procedure for measuring the mass of a biopolymer in a sample by mass spectrometry;
- A database search procedure for searching a predetermined database for candidate molecules by matching an observed mass value obtained by said mass measurement procedure with the predetermined database;

- a candidate molecule selection procedure for selecting an arbitrary number of candidate molecules having a high similarity score;
- a mass value calibration procedure for calibrating the observed mass value using the candidate molecules as an internal reference;
- a procedure for calculating relative error between a calibrated mass value of a candidate molecule obtained in a previous procedure and a theoretical mass value in order to determine the standard deviation of such relative error;
- a procedure for determining the tolerance (allowable error) of the database search procedure based on the standard deviation; and
- a procedure for repeating the database search procedure on the basis of the tolerance

The feature that distinguishes the claimed invention from the prior art, as explained in the Background section, is the calibration procedure that is based solely on data processing and that eliminates the need for calibration of the mass spectrometer prior to measurement or the addition of an internal standard to the sample in advance.

Egelhofer (Anal. Chem., 74, 1760-1771, March 3 2002) teaches protein identification method comprising the steps

- measurement procedure for measuring the mass of a biopolymer in a sample by mass spectrometry (see abstract);
- A database search procedure for searching a predetermined database for candidate molecules by matching an observed mass value obtained by

said mass measurement procedure with the predetermined database (p. 1760, right column, first paragraph);

- a candidate molecule selection procedure for selecting an arbitrary number of candidate molecules having a high similarity score (p. 1760, right column, first paragraph);
- a mass value calibration procedure for calibrating the observed mass value using the candidate molecules as an internal reference (p. 1762, right column, first full paragraph);
- a procedure for calculating relative error between a calibrated mass value of a candidate molecule obtained in a previous procedure and a theoretical mass value in order to determine the standard deviation of such relative error (Abstract; p. 1760, right column, first paragraph; p. 1762, bottom through p. 1763; Fig. 3)
- a procedure for determining the tolerance (allowable error) of the database search procedure based on the standard deviation (Abstract; p. 1760, right column, first paragraph; p. 1762, bottom through p. 1763; Fig. 3).

With respect to claim 2 which specifies the calibration procedure, the reference teaches calculation of the relative error (), creating a least square line with respect to a plot of the theoretical mass value and the relative error (see p. 1763, and Fig. 3c-f; and calibrating the observed mass value by subtracting the systematic error from the entire actual measurement values (see p. 1763, right column).

5. Claim 1 is rejected under 35 U.S.C. 102(b) as anticipated by Gobom et al.

Gobom teaches a calibration method for determining masses of peptide fragments (see Abstract). In particular the reference teaches the steps of the instant broad claim 1, such as calibrating observed mass values using candidate molecules as internal references, calculating relative error and standard deviation, and determining allowable error. See p. 3919, left column.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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 Michael Borin, Ph.D.
Primary Examiner
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mlb